

## **REMARKS**

Claim 8 is amended to correct for a typographical error. No new matter has been added.

The presently claimed invention is directed to a sustained release composition comprised of a core, which comprises an active agent, one or more prolamins from about 30% to about 70% of the total weight of the composition and one or more gelling agents from about 5% to about 20% of the total weight of the composition, as recited in claim 1. Claims 3-8 and 18 are dependent upon claim 1. Further, the presently claimed invention is also directed towards a delayed-onset composition comprising a core and a coating, wherein said coating is dry-compressed and comprises one or more prolamins and one or more gelling agents, wherein said one or more prolamins is about 30% to about 100% of the total weight of the coating and said one or more gelling agents is about 0% to about 20% of the total weight of the coating, as recited in claim 9. Claims 10-17 and 19 are dependent upon claim 9. The prolamins are the hydrophobic portion of the composition and the gelling agents are the hydrophilic portion of the composition.

Reconsideration and allowance of the present application in view of the following remarks are respectfully requested.

### **I. CLAIMS 1 AND 3-19 ARE PATENTABLE OVER ROSENTHAL IN VIEW OF BAICHWAL**

The Examiner rejects claims 1, 3-8 and 18 under 35 U.S.C. § 103(a) as allegedly being unpatentable over United States Patent No. 2,895,880 to *Rosenthal* ("*Rosenthal*") in view of United States Patent No. 5,846,563 to *Baichwal* ("*Baichwal*"). Applicants respectfully traverse.

The Examiner states that *Rosenthal* teaches a sustained release composition comprising prolamins in an amount from about 20% to about 45%. (Office Action, p. 2). The Examiner also states that *Rosenthal* teaches that starch may be included in the composition. *Id.* The Examiner states that *Baichwal* teaches a sustained release formulation comprising one or more heteropolysaccharides, a cross-linking agent, an active agent, and a hydrophobic material, such as zein. *Id.* The Examiner alleges that at the time the Applicants' invention was made, it would have been obvious to a person of ordinary skill in the art to modify the sustained release formulation of *Rosenthal* by adding a gelling agent disclosed in

*Baichwal*. (Office Action, p. 3).

In order for an Examiner to establish an obviousness-type rejection the Examiner must show some “suggestion or motivation from the prior art to modify or combine” the reference teachings. MPEP §§2142, 2143. However, where the prior art neither teaches nor suggests the claimed invention, obviousness does not result merely because the prior art could be modified. *In re Laskowski*, 871 F.2d 115, 117, 10 USPQ2d 1397, 1398 (Fed. Cir. 1989); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ2d 1125, 1127 (Fed. Cir. 1984). The prior art reference must suggest the desirability of the modification. Furthermore, the prior art must provide one of ordinary skill in the art with the motivation to make the modifications required to arrive at the claimed invention. *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984). Both the suggestion and expectation of success must be found in the prior art, not in applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991), citing *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

Moreover, as established in prior caselaw, a reference cannot suggest a limitation if it teaches away from the claimed invention. *In re Geisler*, 43 U.S.P.Q.2d 1362, 1366 (Fed. Cir. 1997).

*Baichwal* discloses a sustained-release formulation with an optional hydrophobic material, such as zein, in an amount from about 1% to about 20% by weight of the composition. (Col. 6, lines 30-35). *Baichwal* teaches that a hydrophobic material is added to its sustained-release formulation “to slow the hydration of the gums,” but the amount of hydrophobic material must be in an amount that will slow the rate of release of the medicament “without disrupting the hydrophilic matrix formed upon exposure to an environmental fluid.” (Col. 6, lines 26-33). Thus, one of ordinary skill in the art would not be motivated by *Rosenthal* to combine *Rosenthal* with *Baichwal*, which teaches that amounts greater than 20% by weight of a hydrophobic material may disrupt the hydrophilic matrix of the *Baichwal* sustained-release formulation, since *Rosenthal* teaches a sustained-release composition comprising from about 20% to about 45% prolamin.

Consequently, *Baichwal* actually teaches away from a sustained release composition comprised of an excess of 20% of a hydrophobic material because an amount greater than 20% would disrupt the synergistic value of the gelling agent. (Col. 6, lines 26-35). Therefore, the *Baichwal* reference cannot provide any suggestion, teaching, or

motivation to combine the cited references because *Baichwal* teaches away from a composition containing more than 20% of a hydrophobic material. Teaching away is "strong evidence of nonobviousness." *In re Hedges*, 783 F.2d 1038, 1041, 228 U.S.P.Q. 685, 687 (Fed. Cir. 1986). Therefore, one of ordinary skill in the art would not be motivated to combine the teachings of *Rosenthal* with the teachings of *Baichwal* to achieve the present invention.

Further, in view of *Baichwal*, the prolamin concentration of the present invention is critical. *Baichwal* discloses that increased amounts of hydrophobic material disrupt the hydrophilic matrix of the sustained-release formulation. Therefore, even if one was to combine the teachings of *Rosenthal* and *Baichwal*, based on *Rosenthal*, one of ordinary skill in the art would not expect to achieve a sustained-release composition with high amounts (from about 30% to about 70% by weight of the composition) of hydrophobic material since the hydrophilic matrix would be disrupted. (*see also* paragraph 4 of *Mr. Bagarollo's Declaration*). Therefore, the presently claimed composition as presented in claims 1, 3-8 and 18 provides unexpected results.

For the above reasons, Applicants respectfully submit that the presently claimed invention is not obvious over *Rosenthal* in view of *Baichwal*. Accordingly, it is most respectfully requested that the rejections under 35 U.S.C. § 103(a) be withdrawn, and reconsideration and allowance of claims 1, 3-8 and 18 are respectfully requested.

## **II. CLAIMS 9-17 AND 19 ARE PATENTABLE OVER OSHLACK**

The Examiner rejects claims 9-17 and 19 under 35 U.S.C. § 103(a) as allegedly being unpatentable over United States Patent No. 5,356,467 to *Oshlack et al.* ("*Oshlack*"). Applicants respectfully traverse.

The Examiner rejects claims 9-17 and 19 under 35 U.S.C. § 103(a) as unpatentable over *Oshlack*. (Office Action, p. 4). The Examiner states that *Oshlack* teaches a controlled-release coating comprising zein and pore-forming agents, which are present in an amount of from about 0.1% to about 80%. *Id.* The Examiner also states that *Oshlack* discloses that the core for the coating can be a tablet, sheroid, pellet, microsphere or granule, and a wide variety of active agents can be incorporated into the core. *Id.* The Examiner alleges that at the time the Applicants' invention was made, it would have been obvious to a person of ordinary skill in the art "to prepare a delayed release composition comprising a core

containing an active agent that is coated with a composition comprising a prolamin and a gelling agent.” (Office Action, p. 5). The Examiner further contends that absent a showing of criticality, “the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization.” *Id.*

The concentration range of one or more prolamins used in the presently-claimed invention is critical. One of ordinary skill in the art would recognize that *Oshlack* teaches that “[t]he upper limit of zein in the zein dispersions of the [*Oshlack*] invention are zein concentrations of about 10% w/v.” (Col. 6, lines 26-28). *Oshlack* further teaches that his invention “is related to an aqueous dispersion of zein, the aqueous dispersion comprising from about 0.1 to about 10 percent zein.” (Col. 3, lines 54-57). *Oshlack* discloses that “[h]igher concentrations have been found to result in the formation of agglomerates.” (Col. 6, 28-29). However, the present invention, as presented in claim 9, comprises one or more prolamins in a critical amount of about 30% to about 100% of the total weight of the coating. (see paragraph 5 of *Mr. Bagarollo’s Declaration*). Therefore, the prolamin concentration range of about 30% to about 100% of the total weight of the coating, as claimed in claim 9, is critical in view of *Oshlack*.

For the above reasons, Applicants respectfully submit that the presently claimed invention is not obvious over *Oshlack*. Accordingly, it is most respectfully requested that the rejections under 35 U.S.C. § 103(a) be withdrawn, and reconsideration and allowance of claims 9-17 and 19 are respectfully requested.

### III. CONCLUSION

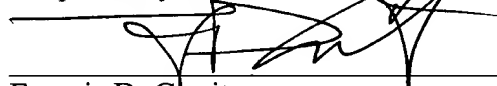
Applicants believe that each ground for rejection of the pending claims has been successfully overcome. Accordingly, Applicants respectfully request that the following rejections be withdrawn: (1) claims 1, 3-8 and 18 as unpatentable over *Rosenthal* in view of *Baichwal* under 35 U.S.C. § 103(a) and (2) claims 9-17 and 19 as unpatentable over *Oshlack* under 35 U.S.C. § 103(a).

Applicants believe that no fee is due in connection with this amendment (other than for the Petition for Extension of Time submitted separately herewith). However, should the Patent Office determine that a fee is due, please charge the required amount to Jones Day Deposit Account 50-3013.

Applicants submit that the entire application is now in condition for allowance. The Examiner is invited to telephone the undersigned should any issues remain.

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Respectfully submitted,



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